Date		Significant Activity
04/15/86 PIMS	ORIG	To FDA: Original IDE submission
05/14/86 PIMS	ORIG	From FDA: IDE G860065, Original application deficient: 1) describe the chemical composition of silicone material, 2) submit an environmental assessment.
06/09/86 PIMS	S001	To CDRH: IDE G860065/S001, Response to letter dated 05/14/86.
07/02/86 PIMS	S001	From FDA: IDE G860065/S001, Deficiencies corrected, application approved.
10/08/86 PIMS	MEMO	Memo from Pete Lord, MMT, regarding the "Manual Revision for Implant Procedure".
12/23/86 PIMS	LTR	Letter from Dr. Christopher Saudek, regarding a second patient whose PPU was malfunctioning.
01/21/87 PIMS	**	To CDRH: IDE G860065, Report of an adverse event involving tissue growth on the catheter with patient DRW.
02/03/87 PIMS	LTR	Letter from Dr. A. Charles, Univ of Calif, Irvine: Request to modify Protocol 301 to include implanting intra- or intermuscularly.
02/17/87 PIMS	MEMO	Memo from Pete Lord: Site change for UCI Clinical Investigator to Medical Center of Garden Grove.
02/20/87 PIMS	LTR	Letter from Christopher Saudek, MD: Notification of PPU malfunction #2.
02/21/87 PIMS	LTR	Letter from Christopher Saudek, MD: Notification of PPU malfunction #3.
02/25/87 PIMS	S002	To ODE: IDE G860065/S002, 1) Change of battery type and nylon case, 2) the option to implant intramuscularly, 3) investigational site change to UC Irvine, 4) change in procedure for flushing of the reservoir of the implantable pump prior to implentatlon
03/02/87 PIMS	S003	To ODE: IDE G860065/S003, Notification of the first implant, IRB approval letter, and copy of the Informed Consent.
03/09/87 PIMS	MEMO	Memo from A.F. Hogrefe: Regarding PPU failures during PIMS rials.
03/09/87 PIMS	S004	To ODE: IDE G860065/S004, Supplement to replace the first generation PPU with a second generation unit and a 9-volt battery.
03/10/87 PIMS	S005	To ODE IDE G860065/S005. Notifying the administration of a name change from Pacesetter Infusion LTD., to MiniMed Technologies, Inc.
03/12/87 PIMS	S002	From FDA: IDE G860065/S002. Supplement is deficient, additional information requested.
03/23/87 PIMS	LTR	Letter from C. Saudek, MD: Minor change to operative procedure to withdraw 0.5 ml of insulin instead of pumping 200 pulses of insulin out.
03/23/87 PIMS	LTR	Letter from C. Saudek, MD: Regarding 3 PPU malfunctions.
03/23/87 PIMS	S006	To ODE IDE G860065/S006, Amendment to Protocol 301 to Section 10, Revision to Patient Manual, Physicians Manual, and Supplement to Physicians Manual.
04/02/87 PIMS	LTR	Letter from Jean-Louis Selam, MD: Regarding discussions with the FDA on the PIMS working group meeting.
04/06/87 PIMS	LTR	Letter from Thomas Hendrix, MD: Regarding the Joint Committees decision on the clinical investigation of the PIMS.
04/06/87 PIMS	S007	To CDRH: IDE G860065/S007, Response to letter dated March 12 1987, additional information on the procedure for priming pumps to remove shipping fluids, changes in the switches and battery for PPUs, and change in Investigational Site.
04/14/87 RIMS	LTR	Letter from the Human Subjects Committee at AMI Medical Center of Garden Grove: Changes made to the IDE are approved.
04/16/87 PIMS	S008	To CDRH: IDE G860065/S008, Copies of letters from the IRBs at Johns Hopkins University and The Medical Center of Garden Grove approving the Protocol changes referenced in a supplement dated 2/25/87.

04/24/87 PIMS	S007	From FDA: IDE G860065/S007, Supplement is approved, deficiencies cited in March 12, 1987 letter corrected.
05/01/87 PIMS	LTR	Letter from OMNICA: Evaluation and repair of MM 180 IPP S/N 110.
05/15/87 PIMS	S009	To ODE: IDE G860065/S009, Inoperative DIRL Sensor on the pump did not present a problem for the patient. There is a second safeguard designed to prevent over delivery of insulin.
06/12/87 PIMS	S009	From FDA: IDE G860065/S009, Regarding the DIRL Sensor, additional information requested.
06/12/87 PIMS	S010	To ODE: IDE G860065/S010, Notification of a malfunction of the Mute Button.
06/17/87 PIMS	**	To CDRH: IDE G860065, Report of an adverse event due to premature battery depletion on patient SFZ.
07/02/87 PIMS	S010	From FDA: IDE G860065/S010, Additional information required.
07/14/87 PIMS	S012	To ODE: IDE G860065/S012, Response to Administration's letter dated 6/12/87 regarding the DIRL Sensor.
07/20/87 PIMS	S013	To ODE: IDE G860065/S013, Depletion of the battery and a drain on the electronics of the pump.
07/22/87 PIMS	**	To FDA: IDE G860065, Response to FDA letter dated 6/12/87, subject: the mutebutton.
08/14/87 PIMS	S012	From FDA: IDE G860065/S012, The DIRL Circuit, additional information required.
08/17/87 PIMS	**	To CDRH: IDE G860065, Reporting that a patient with a PIMS pump is experiencing encapsulation of the catheter and the pump and catheter will be removed.
08/18/87 PIMS	**	To CDRH: IDE G860065. Advising FDA that a patient's (#SFZ) premature battery depletion was due to the N1 signal line of array A2.
08/20/87 PIMS	S013	From FDA: IDE G860065/S013, Additional information required, supplement disapproved.
08/21/87 PIMS	S014	From FDA: IDE G860065/5014, Additional information required.
09/08/87 PIMS	**	To FDA: IDE G860065, Response to letter dated 8/14/87, elimination of the DIRL Circuit from PIMS pump.
09/08/87	LTR	Letter from UC Irvine: The need for improved diabetes metabolic control to alleviate the current complications.
09/09/87 PIMS	**	To CDRH: IDE C860065, Deficiencies in July 20, 1987, letter will be addressed in a submission on October 20, 198__.
09/09/87 PIMS	**	To CDRH: Response to letter dated August 21, 1987, request for additional information on the revised Patients Manual.
09/30/87 PIMS	S021	To CDRH: IDE G860065/S021, Requesting approval to implant the original PIMS design while waiting for the FDA's approval of the modified design.
10/13/87 MIP	**	To CDRH: IDE G860065, Confirming a meeting to be taking place in the Chesapeake Room of the Parklawn Building on November 17, 1987.
10/15/87 PIMS	S022	To CDRH: IDE G860065/S022, Response to the letter dated August 20, 1987, proposing modifications to the PIMS.
10/22/87 PIMS	LTR	Letter from C. Saudek, MD: A catheter blocked in patient #4.
10/26/87 PIMS	S021	From FDA: IDE G860065/S021, Application deficient for proposing continued implantation of original PIMS.
10/27/87 PIMS	LTR	From FDA: IDE G860065, Notification that the IDE Progress Report is overdue and as a sponsor you are required to submit these annually.
11/05/87 PIMS	LTR	To Medical Center of Garden Grove: Stating that the FDA disapproved implants of the original PIMS design until deficiencies are corrected.
11/06/87 PIMS	**	To CDRH: IDE G860065, Report of a catheter partically obstructed by peritoneal tissue that was repaired with laparoscopy.

11/20/87 PIMS	S022	From FDA: IDE G860065/S022, Supplement remains disapproved and deficiencies listed with respect to 1) software validation, 2) fluid pathway and 3) battery life.
12/09/87 PIMS	**	To FDA: IDE G860065, First Year Progress Report for PIMS.
01/07/88 PIMS	**	To CDRH: IDE G860065, Report that a patient's second catheter appeared to malfunction (patient DL-05) and at the request of the patient, the pump and catheter were removed.
01/21/88 PIMS	**	To CDRH: IDE G860065, Report that lapa scopy surgery was performed to clean the catheter of tissue growth.
02/09/88 PIMS	LTR	Letter from C. Saudek, MD: Ophthalmologic status of MBD, JHH patient #4.
02/24/88 PIMS	LTR	Letter from Jean-Louis Selam, MD: Explained pump from patient LD-03 at UCI/AMI.
02/25/88 PIMS	**	To CDRH: IDE G860065, Report of a 25 year old patient with visual deterioration due to diabetes not apparently linked to the implantation of the MIP.
02/26/88 MIP		To FDA, CDRH. From, MiniMed, William Duffell, re: completed analysis results of catheter, patient DLO5
02/26/88 PIMS	**	To CDRH: IDE G860065, Supplement to advise the FDA that patient LD-03 had experienced an encapsulated catheter and received a new catheter on November 25, 1987.
07/07/88 MIP	S032	From FDA: IDE G860065/S032, Application approved and the investigation can start where there is IRB approval.
08/11/88 MIP	**	To CDRH: IDE G860065, Plan for obtaining data to support a PMA for MIP.
08/15/88 MIP	S033	To CDRH: IDE G860065/5033, Copy of Protocol 302 for the Clinical Investigation.
09/16/88 MIP	S033	From FDA: IDE G860065/S033, Supplement for Protocol 302 approved.
09/16/88 MIP	S034	From FDA: IDE G860065/S034, Supplement for Protocol 302 approved.
10/18/88 MIP	S035	To CDRH: IDE G860065/S035, A copy of the Informed Consent Form for Protocol 302.
11/18/88 MIP	S035	From FDA: IDE G860065/S035, Supplement approved for the informed consent form which indicates there may be costs to the patient in the study.
11/29/88 MIP	S037	To CDRH: IDE G860065/S037, Copy of an updated Informed Consent Form with the section pertaining to the costs to the patient rewritten.
11/30/88 MIP	S036	To CDRH: IDE G860065/S036, Revision to Protocol 302 (eight revisions with rationale listed).
01/04/89 MIP	S036	From FDA: IDE G860065/S036, Supplement approved for changes to Protocol 302.
01/04/89 MIP	S037	From FDA: IDE G860065/S037, Application approved, updated patients section pertaining to possible costs to the patient.
02/28/89 PIMS	**	To CDRH: IDE G860065. Report of two patient adverse events for patients JG-10 and patient TG-06.
03/15/89 PIMS	**	To ODE: IDE G860065, Report of an adverse event involving skin erosion and pump explant.
06/12/89 PIMS	LTR	Letter torn C. Saudek, MD: A PIMS patient with an adverse event.
07/13/89 PIMS	LTR	Letter torn C. Saudek, MD: Report of a PIMS patient with an adverse event.
07/14/89 PIMS	LTR	From FDA: Letter to IDE Sponsors indicating that FDA does not routinely acknowledge the receipt of IDE supplements.
07/17/89 PIMS	**	To ODE: IDE G860065, Report of an adverse event involving elevated blood glucose levels.

07/24/89	PIMS	S040	From FDA: Acknowledging receipt of supplement.
08/14/89	PIMS	LTR	Letter from Christopher Saudek, MD: Regarding a PIMS adverse event.
09/11/89	PIMS	**	To ODE: Notification of an unanticipated adverse event with patient TJM
09/20/89	PIMS	LTR	To Chairman Joint Committee: Letter from C. Saudek, MD regarding a PIMS adverse event.
09/27/89	PIMS	S041	To ODE: IDE G860065/S041, Report of an adverse event involving a PIMS patient with elevated blood glucose levels.
10/27/89	PIMS	S041	From FDA: IDE G860065/S041, Requesting a progress report to access adverse device defects.
11/22/89	MIP	**	To ODE: IDE G860065, Progress Report and a list of investigators signed-up for the study.
01/17/90			Implant
01/25/90			Implant
02/02/90			Implant
02/02/90			Implant
02/07/90			Implant
02/16/90			Implant
02/16/90			Implant
02/21/90			Implant
02/22/90			Implant
02/26/90			Implant
03/23/90	MIP	**	To CDRH: IDE G860065, Notice to the administration of a PIMS patient that had become pregnant and that the pump will be explanted within the month.
04/03/90			Implant
04/03/90			Implant
04/12/90			Implant
04/12/90			Implant
04/27/90	MIP	LTR	Letter from Dr. Selam: Rationale for replacing a MIP (battery depletion rear).
04/30/90			Implant
04/30/90			Implant
05/02/90			Implant
05/04/90			Implant
05/16/90			Implant
05/16/90			Implant
05/17/90			Implant
05/17/90			Implant
05/24/90			Implant
05/30/90			Implant
06/01/90	MIP	MEMO	To Investigators MIP Trials: Clarifying the inclusion/exclusion criteria for retinopathy, contained in Protocol 302.
06/12/90	MIP	LTR	Letter from Christopher Saudek, MD; Requesting deviation from Protocol 302 for diabetic retinopathy for two patients doing well on PIMS.
06/12/90	MIP	S045	To CDRH: IDE G860065/S045, Request to expand to Phase II of (he study, with 25 sites and 200 patients.
07/06/90	MIP	**	To CDRH: IDE G860065 Progress Report and current investigator list.
07/18/90	MIP	S045	From FDA: IDE G860065/S045, Supplement to increase patient population approved.
07/24/90			Implant
07/24/90			Implant

07/31/90 MIP	S047	To CDRH: IDE G860065/S047, Amendment to Protocol 302, "The use of The MiniMed Implantable Infusion System in the Treatment of Patients with Type 1 Diabetes Mellitus".
08/01/90 MIP	801 e	To CDRH: Export Approval for Investigational Device (6860065, MIP) to France.
08/13/90 MIP	S049	To CDRH: IDE G860065/S049, Requesting a deviation from the retinopathy exclusion criteria of Protocol 302, for 3 patients.
08/14/90 MIP	**	To CDRH; IDE G860065. Report of patient KMS-01 with an adverse device defect, obstruction of the pump or catheter.
08/15/90 MIP	**	To CDRH: IDE G860065, Response to Agency's questions and addendum to progress report for IDE 6860065.
08/27/90 MIP	LTR	Letter from Christopher Saudek, MD: Regarding PIMS patient Keith B. Cyphert needing deviation from Protocol for diabetic retinopathy.
08/28/90		Explant
08/28/90		Implant
09/05/90		Implant
09/06/90 MIP	S047	From FDA: IDE G860065/S047, Supplement approved proposing new patient exclusion criteria and modification of informed consent.
09/10/90 MIP	**	To CDRH: IDE G860065, Report of an unanticipated adverse effect due to pump not communicating with the DPU or the site's back up PPC.
09/11/90 MIP	S052	To CDRH: IDE G860065/S052, Documentation of an additional patient (total of 4 PIMS patients) that needs deviation from Protocol 302 to receive a MIP pump.
09/13/90 MIP	S049	From FDA: IDE G860065/S049, Supplement approved for deviation from Protocol 302 for retinopathy exclusion criteria for two patients.
09/18/90		Explant
09/24/90 MIP	**	To CDRH: IDE G860065, Report of a device complication incident due to obstruction of either the catheter or the pump.
09/25/90		Implant
09/25/90		Implant
09/26/90		Implant
09/27/90		Implant
09/28/90 MIP	**	To CDRH: IDE G860065, Report of a device explant on patient VLC-03 due to an infection.
10/02/90		Implant
10/02/90		Explant
10/03/90 MIP	S055	To CDRH: IDE G860065/S055, Statistical Analysis Plan and request to expand the study as originally requested, to 25 sites and 200 patients.
10/10/90		Implant
10/12/90 MIP	S052	From FDA: IDE G860065/S052, Supplement approved for deviation from Protocol for patient KBC.
10/17/90 MIP	801e	From FDA: Certificate for Products for Export to Germany for various models.
10/24/90		Implant
10/24/90		Implant
10/30/90		Implant
11/01/90		Implant
11/01/90		Implant
11/02/90 MIP	S055	From FDA: IDE G860065/S055, Approval to expand the study to 15 investigational sites and 100 devices.
11/08/90		Implant

11/13/90 MIP	S056	To CDRH: IDE G860065/S056, Summary of Safety and Efficacy for 64 patients and 14 sites with 322 months of experience requesting expansion to the Veterans Affairs Administration.
11/16/90		Implant
11/27/90		Implant
11/28/90		Implant
11/28/90		Implant
12/04/90		Implant
12/04/90		Implant
12/05/90		Implant
12/05/90		Implant
12/05/90		Implant
12/12/90		Implant
12/13/90		Implant
12/13/90		Implant
12/13/90		Implant
12/14/90 MIP	S057	To CDRH: IDE G860065/S057, Enclosing additional data, as listed in the Agency's letter dated November 2, 1990, and requesting expansion of the study to 17 sites and 160 devices.
12/20/90 MIP	**	To CDRH: IDE G860065, Patient VECO2 of France experienced "Pump Stopped-Call Doctor Now' message and required the pump to be explanted.
12/20/90 MIP	S056	From FDA: IDE G860065/S056, Data insufficient, application remains disapproved.
01/02/91		Implant
01/03/91 MIP	S063	From FDA: IDE G860065/S063, Approving an increase from 17 to 18 institutions.
01/09/91		Implant
01/09/91		Implant
01/09/91		Implant
01/11/91 MIP	**	To CDRH: IDE G860065, Summary of data to approve limited expansion of the study.
01/11/91		Implant
01/13/91		Implant
01/14/91 MIP	S057	From FDA: IDE G860065/S057, Approval to expand the study to 160 devices and 17 investigation sites.
01/22/91		Implant
01/22/91		Implant
01/23/91		Implant
01/23/91		Implant
01/24/91		Implant
01/29/91		Implant
02/11/91 MIP	S059	To CDRH: IDE G860065/S059, Response to the Agency's letter dated January 14, 1991, requesting information to show that a minimum of 10 weeks is sufficient to demonstrate permanent stabilization of HbA1c.
02/13/91		Implant
02/20/91		Implant
02/20/91		Implant
02/21/91		Implant
02/25/91		Implant
02/27/91		Implant

03/14/91	MIP	S059	From FDA: IDE G860065/S059, Conditional approval for stabilization of HbA1c.
03/14/91	MIP	S059	From FDA: IDE G860065/S059, Conditional approval for stabilization of HbA1c.
03/15/91			Implant
03/19/91			Implant
03/19/91			Implant
03/28/91	MIP	**	To CDRH: IDE G860065, Report of laparascopy surgery due to underdelivery of insulin caused from a mechanical failure in the pumping mechanism on patient FMA16 of France.
03/28/91	MIP	**	To CDRH: IDE G860065, Report of laparascopy surgery due to underdelivery of insulin caused from a mechanical failure in the pumping mechanism on patient FMA16 of France.
04/15/91			Implant
04/15/91			Implant
04/17/91			Implant
04/18/91	MIP	**	To CDRH: IDE G860065, Follow-up letter to confirm that quarterly reports are due in Mid-May after the PMA is submitted and will include data from The Veterans Affairs and MMT.
04/18/91	MIP	**	To CDRH: IDE G860065, Follow-up letter to confirm that quarterly reports are due in Mid-May after the PMA is submitted and will include data from The Veterans Affairs and MMT.
04/23/91			Implant
04/25/91			Implant
05/15/91			Implant
05/15/91			Explant
05/17/91			Implant
05/17/91			Explant
05/24/91	MIP	S059	From FDA: DE G860065/S059, Stamped letter replacing the letter sent earlier that was not date stamped.
05/24/91	MIP	S059	From FDA: DE G860065/S059, Stamped letter replacing the letter sent earlier that was not date stamped.
05/29/91			Implant
05/29/91			Implant
06/05/91			Implant
06/05/91			Implant
06/05/91			Implant
06/05/91			Implant
06/13/91			Implant
06/14/91			Implant
06/14/91			Implant
07/02/91			Implant
07/02/91			Implant
07/10/91			Implant
07/10/91			Implant
07/12/91			Implant
07/17/91			Implant
07/17/91			Implant
07/23/91			Implant
08/05/91			Explant
08/05/91			Implant

08/05/91			Implant
08/05/91			Implant
08/14/91			Implant
08/15/91			Implant
08/21/91			Implant
08/27/91			Implant
09/12/91			Implant
09/16/91			Implant
09/16/91			Implant
09/16/91			Implant
09/18/91	MIP	801e	From FDA: Approval to export MIP to Belgium and Italy.
09/18/91	MMT 4001	801e	From FDA: Request to export MMT-4001 to Ireland, Germany and Austria is denied. Obtain approval from proper official sources.
09/19/91	MIP	**	To CDRH: IDE G860065, Analysis results for incidents previously reported.
09/19/91	MIP	**	To CDRH: IDE G860065, Analysis results for incidents previously reported.
09/24/91			Implant
09/25/91			Implant
10/03/91			Implant
10/07/91			Implant
10/08/91			Implant
10/08/91			Implant
10/29/91			Implant
10/29/91			Implant
11/18/91			Implant
11/18/91			Implant
11/19/91			Implant
12/04/91			Implant
12/12/91			Implant
01/08/92			Implant
01/09/92			Explant
01/09/92			Explant
01/17/92			Implant
01/17/92			Implant
01/22/92			Implant
01/27/92			Implant
01/27/92			Implant
02/19/92	MIP	LTR	From FDA: Letter to MiniMed concerning meeting minutes regarding NDA and PMA submitted together as two companion entities.
02/19/92	MIP	LTR	From FDA: Letter to MiniMed concerning meeting minutes regarding NDA and PMA submitted together as two companion entities.
02/24/92			Implant
02/24/92			Implant
02/26/92			Implant
02/26/92			Implant
02/26/92			Implant
03/01/92			Implant
03/06/92			Explant
03/17/92			Implant

03/17/92		Implant
03/20/92 MIP	S065	To CDRH: DE G860065/S065, Supplement to list changes to Protocol 302 and changes to the refill kit and procedure.
03/23/92		Implant
03/28/92		Implant
04/22/92 MIP	S064	From FDA: DE G860065/S064, Supplement regarding pump refill kit MMT-4100 is approved.
04/22/92 MIP	S065	From FDA: IDE G880065/S065, Supplement proposing changes to Protocol 302 for the refill kit requires additional information.
04/22/92 MIP	S066	From FDA: IDE G860065/S066, Approval to incorporate the refill kit MMT-41 00, into the study.
04/27/92		Implant
04/27/92		Implant
05/01/92		Implant
05/05/92		Implant
05/12/92		Implant
05/12/92		Implant
05/18/92		Implant
05/18/92		Implant
05/20/92		Implant
06/03/92		Implant
06/09/92 MIP	S069	To CDRH: IDE G860065, Notice of an explanted pump cue to polymeric insulin on the sealing seal and the rubber valve seal had signs of excessive wear.
06/25/92		Explant
06/25/92		Implant
06/25/92		Implant
06/25/92		Implant
07/06/92		Explant
07/06/92		Implant
07/13/92 MIP	S070	To CDRH: DE G860065. Reporting two adverse effects relating to the MIP. Both patients had the MIP for over two years. Both patients needed a replacement pump and catheter.
07/15/92 MIP	MEMO	Memo from John Schultz Re: Explants due to pump backflow.
07/23/92 MIP	**	To CDRH: DE G860065, Supplement reporting an unanticipated adverse devise effect relating to the MiniMed Implantable Pump (MIP).
07/29/92		Implant
08/14/92 MIP	S70	From FDA re: 3 unanticipated adverse device effects at Baltimore & Toulouse.
08/21/92 MIP	S70	To FDA, CDRH. From Jeff Greiner. re: response to letter of August 14, 1992 regarding unanticipated adverse events.
08/24/92 MIP	S70	To FDA, CDRH. From Jeff Greiner. re: (DRAFT) letter concerning proposed changes to comply with backflow phenomenon and informed consent revisions.
08/28/92 MIP	LTR	Letter to Department of Veterans Affairs: Notification of an Adverse event for patient O7TCSO5.
08/28/92 MIP	S70	To: CDRH: Ltr to Paul R. Beninger, re: Telep. conversation w/Ms Matten on 8/27/92 - 1) copy of a ltr to centers and their IRBs, 2) report on backflow anomaly.
08/31/92 MIP	**	To CDRH: IDE G860065, Report of two unanticipated adverse device effects for patients O9MXI-07 and IHMAYO3.

08/31/92 MIP	LTR	Letter from Christopher Seudek, MD: Request to replace the pump in patient PC 16 (if necessary at time of surgery).
09/02/92 MIP	LTR	Letter from Richard Levy. MD: Request for a replacement pump on patient 0305LLE.
09/04/92		Implant
09/04/92		Explant
09/08/92 MIP	LTR	Letter from Robert Creech, MD: Requesting a replacement pump for patient VDS01.
09/08/92 MIP	LTR	Letter from Robert Creech, MD: Requesting a replacement pump for patient TCS05.
09/10/92 MIP	**	To CDRH: IDE G860065, Report of an adverse event due to a blocked catheter tip for patient 0516PGC.
09/11/92 MIP	LTR	Letter from Christopher Saudek, MD: Requesting a replacement pump for patient MUR17.
09/15/92		Explant
09/15/92		Implant
09/15/92		Explant
09/15/92		Implant
09/17/92 MIP	**	To CDRH: IDE G860065, Report of an unanticipated adverse device effect due to a blocked catheter for patient 0305LLE.
09/17/92 MIP	**	To CDRH: IDE G880065, Report of an unanticipated adverse device effect due to a blocked catheter tip for patient 05I7MJR.
09/21/92 MIP	LTR	Letter from Richard Levy, MD: Requesting a replacement pump for patient 0301KMS.
09/21/92 MIP	MDR	From FDA: Requesting additional information on MDR reports.
09/21/92 MIP	S083	To CDRH: IDE G860065/3083, Report of an unanticipated adverse device effect due to a blocked catheter for patient 652-042.
09/22/92 MIP	**	To CDRH: IDE G860065, Notifying the Agency of exceptions to Protocol 302, replacing MIPs.
09/22/92		Implant
09/22/92		Explant
09/28/92 MIP	**	To CDRH: IDE G860065, Report of an unanticipated adverse device effect due to possible catheter blockage for patient 0701/DS.
09/29/92		Explant
09/29/92		Implant
09/29/92		Implant
09/29/92		Explant
10/02/92 MIP	**	To CDRH: IDE G860065, Report and a letter from a physician of a planned intervention for the patients health reasons.
10/02/92 MIP	**	To CDRH: IDE G860065, Report of an adverse device effect due to moderate hyperglycemia for patient 05I2MJP.
10/02/92 MIP	S76	From FDA: IDE G860065/S76 Request to resume new implantations is disapproved. Rinse procedure is conditionally approved or patients already implanted.
10/02/92 MIP	S76	To J. Greiner. From FDA CDRH. re: response and conditions regarding supplement to the IDE application. (NaOH/potassium phosphate rinse)
10/06/92		Explant
10/06/92		Implant
10/06/92		Explant
10/06/92		Implant
10/09/92 MIP	LTR	Letter from Paul Davidson, MD: Requesting a replacement pump for patient 0805KLD.

10/13/92 MIP	**	To CDRH: IDE G860065. Reporting two adverse events for patients 0301KMS and 0705TCS, due to surgical intervention and "pump stopped" message.
10/14/92		Implant
10/14/92		Explant
10/15/92 MIP	**	To CDRH: IDE G860065, Letters from investigators that show that backflow anomaly does not cause unreasonable risk to patients.
10/15/92 MIP	**	To CDRH: IDE G860065, Report of an adverse device effect due to catheter occlusion for patient 0805KLD.
10/21/92 MIP	S095	To CDRH: IDE G860065/S095, Response to letter dated October 2, 1992 involving the rinse procedure.
10/23/92 MIP	S083	From FDA: IDE G860065/S083, Requesting additional information in regards to an adverse event.
10/29/92 MIP	**	To CDRH: IDE G860065, Per agreement with the Agency dated October 21, 1992, follow-up report to the recently approved rinse procedure.
11/11/92		Explant
11/13/92 MIP	**	To CDRH: IDE G860065, Per agreement with the Agency dated October 21, 1992, patient follow-up report to the rinse procedure.
11/16/92 MIP		To:CDRH Response to Conditional Approval Letter, dated October 2, 1992.
11/16/92		Explant
11/23/92 MIP	**	To CDRH: IDE G860065, Per agreement with the Agency dated October 21, 1992, follow-up to recently approved rinse procedure.
11/25/92 MIP	LTR	Letter from J.J. Prendergast, MD: Requesting a replacement pump due to her pump shifting and tearing sutures 1808 CCM.
11/25/92 MIP	S096	From FDA: IDE G860065/S096, Requesting additional information for the MIP and notice to MMT that the supplement seems to misrepresent the device as being safe and effective.
11/30/92		Explant
11/30/92		Implant
12/03/92		Explant
12/08/92 MIP	**	To CDRH: IDE G860065. Per agreement with the Agency dated October 21, 1992, follow-up clinical report of rinse procedure, additional information requested by Agency.
12/08/92 MIP	LTR	Letter from Christopher Saudek, MD: Requesting a pump for patient 0515RDG to replace his MIP.
12/09/92 MIP	S103	To CDRH: IDE G860065/S103, Attaching a Clinical Investigator's letter documenting a replacement pump and additional surgery.
12/15/92		Explant
12/15/92		Implant
12/16/92 MIP	S104	To CDRH: IDE G860065/S104, Enclosing a letter from a Clinical Investigator concerning planned intervention with the MIP.
12/17/92 MIP	S099	From FDA: IDE G860065/S099, Request to resume new implants disapproved and additional rinse procedure data requested.
12/23/92 MIP	S106	To CDRH: IDE G860065/S106, Supplement proposing justification for resuming new implants.
12/29/92		Implant
01/04/93 MIP	**	To CDRH: IDE G860065, Per agreement with the Agency dated October 21, 1992, follow-up clinical report of the rinse procedure.
01/05/93 MIP	**	To CDRH: Letter from St. Thomas Hospital regarding the rinse procedure that is scheduled for volunteer patient 03.

01/06/93 MIP	**	To CDRH: IDE G860065, letter to a patient from the Diabetes Institute regarding the study.
01/08/93 MIP	S103	From FDA: IDE G860065/S103, Letter informing MMT that replacement device implants are counted against the waiver limit (160)
01/13/93 MIP	**	To CDRH: IDE G860065, letter to MMT regarding one of the first implant patients battery failed and pump shutdown, expecting to explant her pump.
01/15/93 MIP	S104	From FDA: IDE G860065/S104, regarding unanticipated adverse events, more information requested.
01/21/93		Explant
01/22/93 MIP	LTR	Letter from Diabetes Institute regarding their decision not to accept replacement pumps.
01/22/93 MIP	S106	From FDA: IDE G860065/S106, proposal to resume terminated studies approved, limited to 18 institutions and 160 subjects.
01/25/93 MIP	S109	From FDA: IDE G860065/S109, Deficiencies corrected, application approved - resumption of implants.
01/25/93 MIP	S110	To CDRH: IDE G860065/S110, Per agreement with the Agency dated October 21, 1992, follow-up of the Clinical Report to the rinse procedure.
01/25/93		Explant
01/25/93		Explant
01/26/93 MIP	S108	To CDRH: IDE G860065/S108, Request to increase patient waiver limit in the study, data on battery depletion.
01/27/93 MIP	LTR	To MMT: Letter from Dr. J.J. Prendergast explaining replacing a MIP for a patient while FDA has suspended pump implantation.
01/27/93 MIP	S111	To CDRH: IDE G860065/S111, Per agreement with the Agency dated October 21. 1992, follow-up of the Clinical Report to the rinse procedure.
01/27/93		Explant
01/29/93 MIP	S112	To CDRH: IDE G860065/S112, Request to add a sub-protocol for patients in high attitude areas (above 8,000 feet).
02/01/93 MIP	LTR	Dear Glucose User, letter to patients for using the glucometer in high altitudes.
02/02/93 MIP	**	To CDRH: IDE G860065, Response to request for additional information concerning Dr. J.J. Prendergast's patient CLM08 (not RDG15).
02/02/93 MIP	S113	To CDRH: IDE G860065/S113, Response to the deficiencies in a letter dated December 17, 1992.
02/02/93 MIP	S115	To CDRH: IDE G860065/S115, Follow-up of (he Clinical Report to the rinse procedure.
02/07/93 MIP	LTR	To CDRH: Letter from Dr. Christopher Saudek, Johns Hopkins Univ regarding the NaOH rinse.
02/10/93 MIP	S116	To CDRH: IDE G860065/S116, Follow-up of the Clinical Report to the rinse procedure.
02/15/93 MIP	S117	To CDRH: IDE G860065/S117, Follow-up of the Clinical Report to the rinse procedure.
02/18/93		Explant
02/18/93		Explant
02/18/93		Implant
02/18/93		Implant
02/23/93 MIP	LTR	Letter from St Thomas Hospital regarding the Alkaline Rinse Procedure.
02/23/93 MIP	S118	To CDRH: IDE G860065/S118, Report of post NaOH Rinse Refill Results.
02/25/93 MIP	S108	From FDA: IDE G860065/S108, supplement proposing an increase in patient population approved.

02/26/93 MIP	**	To CDRH: IDE G860065, Follow-up to conversations on 2/23 and 2/26/93 enclosing letters from investigators regarding replacement pumps and their line of reasoning.
02/26/93 MIP	S--	From FDA: IDE G860065/S110, 111, 115, 116, and 117, the rinse procedure, the Agency is requesting quarterly reports on this procedure.
02/26/93 MIP	S--	From FDA: IDE G860065/S110, 111, 115, 116, and 117, the rinse procedure, the Agency is requesting quarterly reports on this procedure.
03/01/93 MIP	S112	From FDA: IDE G860065/S112, Conditional approval for a sub-protocol (high attitude areas).
03/04/93 MIP	S113	From FDA: IDE G860065/S113, Application for rinse procedure approved.
03/05/93 MIP	**	To CDRH: Report of a deviation from the investigational plan and a change In the home glucose monitors.
03/08/93		Implant
03/10/93 MIP	LTR	From Diabetes Treatment Center: Letter to MMT proposing to change the glucometer to One Touch II for patients implanted with MIP.
03/11/93		Implant
03/16/93		Implant
03/16/93		Explant
03/17/93		Explant
03/19/93		Implant
03/19/93		Explant
03/26/93 MIP	S118	From FDA: IDE G860065/S118, Approval for 13 institutions and 318 subjects. Post-refill data on four patients is deficient, additional information required.
03/30/93		Implant
03/30/93		Explant
04/06/93		Explant
04/06/93		Implant
04/15/93 MIP	S120	To IDE Staff: IDE G860065/S120, Response to letter regarding the sub-protocol and post-refill analysis of the first four rinse patients.
04/19/93		Explant
04/20/93 MIP	**	To CDRH: Supplement to IDE G860065, Mode MIP - Adverse Event Report due to message "pump stopped, call doctor" with patient 03O0JGD.
04/20/93		Explant
04/21/93		Explant
04/21/93		Implant
04/21/93		Explant
04/21/93		Implant
04/23/93		Explant
04/23/93		Explant
05/04/93		Explant
05/04/93		Implant
05/04/93		Implant
05/05/93		Explant
05/12/93		Explant
05/12/93		Implant
05/13/93 MIP	S120	From FDA: IDE G860065/S120. deficiencies sited in March 1, 1993 letter corrected. Application approved and investigation at Rose Medical Center in Denver may continue.
05/19/93		Implant

05/19/93		Explant
05/19/93		Explant
05/19/93		Implant
05/26/93		Implant
05/26/93		Implant
05/27/93 MIP	**	To CDRH: IDE G860065, The investigators decision to deviate from Protocol 302.
05/28/93 MIP	**	To CDRH: IDE G860085, Response to the Agency's letter dated 2/26/93, for additional information regarding the rinse procedure.
05/28/93 MIP	MMR	Medical Monitors Review.
06/02/93		Explant
06/03/93		Explant
06/03/93		Implant
06/03/93		Implant
06/03/93		Explant
06/03/93		Implant
06/03/93		Explant
06/07/93 MIP	**	To CDRH: IDE G860065, Adverse Event Report, MIP, Model Series MIP due to backflow or catheter occlusion with patient 1403HXH.
06/08/93		Explant
06/08/93		Implant
06/17/93 MIP	**	To CDRH: IDE G860065, Adverse Event Repcat, MiniMed Implantable Pump, Model Series MIP.
06/18/93 MIP	S126	To CDRH: IDE G860065/S126, Change in the investigational plan for reduction in data collection and change in home glucose monitors.
06/23/93		Explant
06/23/93		Explant
06/30/93		Explant
06/30/93		Implant
07/06/93		Implant
07/06/93		Explant
07/06/93		Explant
07/07/93		Explant
07/08/93		Explant
07/08/93		Implant
07/14/93 MIP	MMR	Medical Monitors Review.
07/14/93 MIP	S126	From FDA: IDE G860065/S126, Approval for reduction in data collection after 18 months in study, and approval for a change in the home glucose monitors.
07/19/93 MIP	**	To CDRH: Letter from Dr. Christopher Saudek regarding the antibody levels in MIP patients.
07/20/93		Implant
07/20/93		Explant
07/21/93		Implant
07/28/93		Implant
07/30/93		Implant
07/30/93		Explant
08/05/93		Implant
08/05/93		Explant
08/05/93		Implant

08/05/93			Explant
08/12/93			Explant
08/12/93			Implant
08/23/93			Explant
08/24/93			Explant
08/26/93			Explant
08/30/93			Explant
08/31/93			Explant
08/31/93			Explant
08/31/93			Implant
08/31/93			Implant
08/31/93			Implant
08/31/93			Explant
09/01/93			Implant
09/01/93			Explant
09/07/93	MIP	S128	To CDRH: IDE G860065/S128, Second quarterly report on the rinse procedure for Protocol 302 patients and request that the reports be discontinued.
09/13/93			Explant
09/17/93			Explant
09/17/93			Implant
09/17/93			Explant
09/17/93			Implant
09/22/93			Implant
09/22/93			Explant
09/24/93			Implant
09/28/93			Explant
09/28/93			Implant
09/29/93			Explant
09/29/93			Implant
09/29/93			Explant
09/29/93			Implant
09/30/93			Explant
10/07/93	MIP	**	To CDRH: Unanticipated Adverse Event Report with patient 19C3MJC
10/07/93	MIP	S128	From FDA: IDE G860065/S128, Approval to discontinue quarterly reports on the pump rinse procedure.
10/14/93			Explant
10/15/93			Explant
10/15/93			Implant
10/25/93			Implant
10/25/93			Implant
10/28/93			Explant
11/03/93			Explant
11/03/93			Implant
11/04/93	MIP	**	To Adverse Event File: Communication between Jean Ray and Mr. T. Ulatowski, FDA, regarding an adverse event.
11/04/93	MIP	**	To CDRH: Response to the Agency's letter of September 21, 1992 requesting additional information pertaining to adverse events
11/17/93			Explant
11/17/93			Implant

11/17/93		Explant
11/17/93		Explant
11/17/93		Implant
11/17/93		Explant
11/17/93		Implant
11/24/93		Explant
11/24/93		Implant
11/25/93		Implant
11/25/93		Implant
11/25/93		Explant
11/25/93		Explant
12/02/93		Explant
12/02/93		Explant
12/03/93		Explant
12/03/93		Explant
12/14/93 MIP	LTR	From SUMMA: Letter concerning a patients tendency to hyperglycemia.
12/15/93		Implant
12/15/93		Explant
12/15/93		Implant
12/17/93 MIP	**	To CDRH: Requesting for a Protocol Waiver for IDE G860065.
12/21/93		Explant
12/22/93		Explant
12/22/93		Implant
12/22/93		Implant
12/22/93		Explant
12/23/93 MIP	**	To CDRH: Supplement to IDE G860065, MIP, to request approval for a manufacturing change for the MiniMed Implantable Pump, Model Series MIP, for the silicone material vendor as a result of Dow Corning withdrawing it's implant grade silicone from the
12/29/93		Explant
12/29/93		Implant
01/10/94 MIP	MEMO	Memo To MMT from Judi Spell: Risk of intra-surgical rinse procedure.
01/11/94 MIP	MMR	Medical Monitors Review of the rinse procedure.
02/18/94		Explant
02/18/94		Implant
02/22/94 MIP	**	To CDRH: Requesting that IDE G860065 supplement be incorporated by reference in the Special Notification of the Federal Register (Devices Affected by Doiw Corning Withdrawal).
02/23/94		Explant
02/23/94		Implant
02/23/94		Explant
02/23/94		Implant
02/24/94		Explant
02/24/94		Explant
03/09/94 MIP	S132	To CDRH: IDE G860065/S132, Report of an adverse event due to blockage of the catheter.
03/11/94 MIP	MMR	From Alan Marcus, Medical Monitor: Letter stating that the reported rates of catheter occlusion and pump under-delivery have increased during 1993.
03/11/94 MIP	S133	To CDRH: IDE G860065/S133, Notification of an adverse event trend.

03/15/94			Explant
03/15/94			Explant
03/15/94			Implant
03/23/94			Implant
03/23/94			Explant
03/29/94	MIP	**	To CDRH: A copy of a letter from Dr. Christopher Saudek for inclusion in IDE G860065 file regarding antibody levels in MIP patients.
04/07/94			Explant
04/08/94	MIP	S132	From FDA: IDE G860065/S132 Additional information required.
04/13/94	MIP	S133	From FDA: IDE G860065/S133 Additional information required for supplement.
04/18/94	MIP	**	To CDRH: IDE G860065, Report of an unanticipated adverse event.
04/26/94			Implant
04/26/94			Implant
04/29/94			Implant
04/29/94			Explant
05/03/94			Explant
05/03/94			Implant
05/11/94			Implant
05/23/94	MIP	MEMO	From Mary S. Barrass, Clinical Research Supervisor: Analysis of a returned implantable pump.
05/25/94			Implant
05/25/94			Explant
06/09/94	MIP	MMR	Medical Monitor's Review.
06/13/94	MIP	S137	To CDRH: IDE G860065/S137, Supplement to request approval for a manufacturing change for the implantable pump and catheter necessitated by Dow Corning withdrawing it's implant grade silicone material from the market.
06/14/94			Explant
06/22/94			Explant
06/24/94			Implant
07/08/94			Implant
07/08/94			Explant
07/12/94	MMT MIP	**	To CDRH: IDE G860065, Response to two requests for failure analysis of the pump and catheter for patient 1603JAJ.
07/12/94			Explant
07/13/94	MIP	S137	From FDA: IDE 860065/S137, Approval for raw material change from Dow Corning implant grade silicone to NuSil implant grade silicone.
07/19/94			Explant
07/19/94			Implant
07/20/94			Explant
07/21/94	MIP	MMR	From Alan Marcus, Medical Monitor, regarding attainment of good glycemic control.
07/26/94			Implant
07/26/94			Implant
07/26/94			Explant
07/27/94			Explant
07/28/94			Explant
08/03/94			Explant
08/10/94	MIP	**	To CDRH: Annual Progress Report for IDE G860065 for Model Series MIP, MiniMed Implantable Pump.

08/10/94			Explant
08/23/94	MIP	LTR	Fax transmission outlining the FDA requirements of exporting products.
08/24/94	MIP	LTR	Specification sheet for the series MMT4020-4030 intended for use with the MMT 2001 MiniMed Implantable Pump.
09/09/94			Explant
09/09/94			Implant
09/12/94			Explant
09/12/94			Explant
09/13/94			Implant
09/13/94			Implant
09/13/94			Explant
09/13/94			Explant
09/21/94			Implant
09/21/94			Implant
09/21/94			Explant
09/21/94			Explant
09/21/94			Implant
09/25/94			Explant
09/25/94			Explant
09/25/94			Implant
09/25/94			Implant
09/30/94			Explant
09/30/94			Implant
10/04/94			Explant
10/14/94			Explant
10/14/94			Implant
10/21/94	MIP	**	To CDRH: Addendum to Annual Progress Report for 1993 for IDE G860065 to respond to the Agency's questions.
10/26/94	MIP	MMR	Medical Monitor's Review.
10/26/94			Implant
10/26/94			Explant
11/01/94	MIP	S139	To CDRH: IDE G860065/S139, Proposing a change in Protocol 302, to incorporate the SidePort Catheter in the configuration.
11/02/94	MIP	MEMO	Memo to FDA file from Terry Gregg: Export authorization request for the SidePort Catheter was submitted to ODE 9/29194. FDAs relocation caused reviews to be delayed 2 to 3 weeks longer than normal. Will communicate again 11/07/94.
11/07/94			Explant
11/07/94			Explant
11/08/94	SIDE-PORT	MEMO	Memo to FDA file from Terry Gregg: Phone conversation with Patty Alexander of FDA, export authorization had been sent November 7, 1994.
11/08/94	MIP	MEMO	Memo from Terry Gregg: Notification from FDA that approval to export SidePort Catheter to France has been granted.
11/08/94			Explant
11/09/94			Explant
11/09/94			Explant
11/16/94			Explant
11/17/94			Explant

11/18/94	MIP	LTR	From Dr. Saudek, Johns Hopkins, to CDRH concerning the SidePort Catheter with the implantable pump system. The letter contains information to support the system.
11/18/94			Implant
11/18/94			Explant
11/22/94	MIP	MEMO	Memo From Terry Gregg: Extension approval for MIP in France.
11/28/94	MIP	MEMO	Memo to File concerning the SidePort Catheter in MiniMed's effort to obtain CE Mark on the implantable pump system.
12/02/94	SIDE-PORT	S139	From FDA: IDE G860065/S139, Supplement is disapproved and MMT may not implement the change in the investigation. Listed are the deficiencies: 1) Pre-Clinical Evaluation 2) Investigational Plan 3) Patient Consent Form 4) Other information
12/07/94	MIP	**	To CDRH: Per Richard Galgin's request, MiniMed re-submitted the Annual Progress Report for IDE G860065 for the year 1993.
12/15/94			Explant
12/16/94			Explant
12/23/94	MIP		TO: CDRH: SidePort Catheter - response to FDA corresp dated December 2, 1994, an addendum to supplement 139 of IDE.
01/23/95	MIP		Letter to CDRH, Response to telephone conversation with R. Galgin on 1/9/95.
01/26/95	MIP	S141	From FDA: IDE G860065/S141, Conditional approval for SidePort Catheter, request for additional information, statistic plan, quarterly report, warning
02/13/95			Explant
02/14/95			Explant
02/23/95			Explant
02/27/95	MIP	S142	To: CDRH: Response to FDA corresp. dated January 26, 1995 (Supplement S141)
03/31/95	MIP	S143	From CDRH: Rec'd approval ltr to continue investigation. Corrected deficiencies cited in FDA's January 28, 1995.
04/20/95			Implant
04/20/95			Explant
04/21/95	MIP		Ltr to IDE: request from Dr. Parish (CDER) for publication written by Dr. Vague.
04/21/95	MIP	S144	To CDRH: Sent copy of publication for incorporation into the referenced IDE.
05/02/95			Implant
05/02/95			Explant
05/08/95	MIP		Fax to Richard Galgin (FDA): sent entire article written by Dr. Vague.
05/08/95			Explant
05/09/95			Implant
05/09/95			Implant
05/09/95			Explant
05/11/95			Explant
05/12/95			Explant
05/12/95			Implant
05/12/95			Implant
05/12/95			Explant
05/23/95			Explant
05/23/95			Implant
05/24/95			Implant

05/24/95	Explant
05/31/95	Explant
05/31/95	Implant
06/02/95	Implant
06/02/95	Explant
06/02/95	Implant
06/02/95	Explant
06/02/95	Implant
06/20/95	Explant
06/20/95	Implant
06/21/95	Explant
06/21/95	Implant
06/21/95	Implant
06/21/95	Explant
06/29/95	Explant
06/29/95	Implant
06/30/95	Explant
06/30/95	Implant
06/30/95	Implant
07/12/95	Implant
07/12/95	Explant
07/12/95	Implant
07/12/95	Explant
07/13/95 MIP	To: IDE Mail Center, CDRH, FDA. re: quarterly update to IDE G860065, MiniMed Implantable Pump (MIP) Model Series MIF
07/18/95	Explant
07/18/95	Explant
07/18/95	Implant
07/21/95	Implant
07/21/95	Explant
07/21/95	Implant
07/21/95	Explant
07/26/95 MIP	Ltr to IDE - Center for Devices & Radiological Health - Adverse Event, Patient 1014FXM from Montpelier.
08/02/95	Implant
08/02/95	Explant
08/02/95	Implant
08/02/95	Explant
08/02/95	Explant
08/14/95	Explant
08/15/95	Explant
08/25/95	Implant
08/25/95	Explant
08/25/95	Implant
08/25/95	Explant
08/29/95	Explant
08/29/95	Implant
09/12/95 MIP	Ltr to IDE - Minor Modification to Refill Procedure. This was in reference to a telephone call from CDRH, Mr. Richard Galgon on August 7, 1995.

09/19/95	MIP		Ltr to CDRH: In response to an FDA telephone corres with Terry Gregg on August 22, 1995 regarding an addendum to an adverse event report submitted to the Agency on 7/26/95.
09/20/95			Explant
09/26/95			Explant
10/04/95	MIP		Ltr to CDRH: Response to Telephone Inquiry for Vented Refill Syringe.
10/12/95	MIP	S147	From: FDA Supplement proposing change to protocol including a 60cc refill syringe
11/20/95	MIP		Ltr to CDRH: Annual Progress Report, 1994
11/28/95	MIP	S151	Ltr to CDRH: Patient 0802PAM - Adverse Event
11/28/95			Explant
12/06/95			Explant
12/15/95			Explant
12/21/95	MIP		To FDA: Protocol 304 - Kidney Transplant Protocol
01/19/96	MIP	S152	Response from FDA regarding Kidney Transplant Protocol sent on 12/I2/95 - Supplement is approved.
01/22/96			Explant
02/06/96			Explant
02/06/96			Implant
02/08/96	MIP		Ltr to IDE Document Mail Center: Adverse Event Follow-up
02/15/96			Implant
02/15/96			Implant
02/15/96			Explant
02/15/96			Explant
02/20/96			Implant
02/20/96			Explant
03/12/96	MIP		Ltr to IDE Mail Center (HFZ-401): IND 31,981 Modification to Refill Kit - MiniMed Implantable Pump (MIP) (4-05)
03/20/96			Explant
04/09/96	MIP		Ltr to IDE Mail Center (HFZ-401) IND 31,981 Third Quarter Update of Sideport Catheter experience – MiniMed Implantable Pump (MIP)
05/15/96			Explant
05/16/96	MIP		Ltr. to IDE Mail Center (HFZ-401) re: Request for expedited review of Modification to the MiniMed Implantable Pump (MIP) Refill Kit submission
05/20/96			Explant
05/20/96			Explant
05/21/96			Explant
05/21/96			Implant
05/29/96			Explant
06/04/96	4105	S154	From FDA, CDRH. Approval for change in IDE of MMT-4100 to MMT-4105 (vented refill kit)
06/07/96			Implant
06/07/96			Explant
06/21/96			Explant
06/21/96			Implant
07/09/96			Explant
07/09/96			Explant
07/10/96			Explant
07/10/96			Explant
07/17/96			Explant

07/17/96		Implant
07/17/96		Explant
07/17/96		Explant
07/17/96		Implant
07/17/96		Explant
07/17/96		Implant
07/17/96		Implant
07/25/96		Explant
07/25/96		Explant
08/07/96 MIP		To FDA, CDRH. From J. Charlson. re: unanticipated adverse event (loss of telemetry)
08/27/96 MIP	LTR	To FDA, CDRH, IDE Mail Center. From Jean Charlson. re: request for waiver in accordance with CFR 314.90 of HOE PH21 U400 insulin.
08/28/96		Explant
09/17/96		Explant
09/24/96		Implant
09/24/96		Explant
09/30/96		Explant
10/04/96		Explant
10/04/96		Implant
10/04/96		Explant
10/04/96		Implant
10/11/96		Explant
10/17/96		Explant
10/22/96		Explant
10/22/96		Implant
10/22/96		Explant
10/22/96		Implant
10/22/96		Implant
10/28/96 MIP		To FDA. CDRH, Doc. Mail Center. From MiniMed, Jim Wierski. re: Modification to the Catheter Flushing Protocol, MiniMed Implantable Pump (MIP)
10/29/96		Explant
10/29/96		Explant
10/29/96		Implant
11/14/96		Implant
11/14/96		Explant
11/26/96 MIP	S158	From FOA, CDRH, Tim Ulatowski. re: MiniMed, Jim Wierski. re: submission dated 10/28/96, Medication to the Catheter Flushing Protocol, request for additional information with regard to the use of Omnipaque in sideport catheter flushing procedure.
12/04/96		Explant
01/06/97 MIP	S159	From FDA, CDRH, Tim Ulatowski. To: MiniMed, Jean Charlson. re: approval of proposal to use UDEL Polysulfone UDEL P-1 700 in the manufacture of the side port catheter plunger
01/07/97 MIP	S158	To: FDA, CDRH, IDE Document Mail Center. From: MiniMed, Jim Wierski. re: response to additional information requested by Tim Ulatowski regarding Omnipaque and modification to the Catheter Flushing Protocol
01/24/97 MIP		To: IDE Staff, IDE Document Mail Center, FDA. From, Jean Charlson, MiniMed. re: Annual Progress Report, MiniMed Implantable Pump (MIP) Model Series MIP

01/31/97 MIP	S158	To: Jim Wierski, Clinical Research MiniMed. From: FDA, CDRH, Tim Ulatowski. re: Notification of disapproval of IDE Supplement S158, Omnipaque with the sideport catheter
01/31/97 MIP	S160	To: Jim Wierski, Clinical Research MiniMed. From: FDA, CDRH, Tim Ulatowski. re: Notification of disapproval of IDE supplement 5158, Omnipaque. with the sideport catheter
02/06/97		Explant
02/21/97		Explant
02/25/97		Explant
03/11/97		Explant
03/21/97		Explant
04/11/97 MIP		To: FDA, CDRH, IDE Mail Center. From: MiniMed, Jean Charlson. re: supplement submission of proposed manufacturing change to the MiniMed Implantable Pump (MIP- model 2001)
05/05/97 MIP		To: FDA, CDRH, Mf. V. Nakayama. From: MiniMed, Jean Charlson. re: response to reviewer's questions regarding PCIP
05/13/97 MIP	S163	From: FDA, CDRH, T. Ulatowski. To: MiniMed, Clinical Programs, Jean Charlson. re: Approval of supplement to the IDE regarding use of Genapol PF10 coating.
06/03/97 MIP		To: FDA, CDRH, IDE Mail Center. From: Gerda Resch, MiniMed. re: request for consideration for a change in sterilization process in manufacture of MiniMed Implantable Pump (MIP)
06/17/97 MIP		To: FDA, CDRH, IDE Mail Center (HFZ-401). From: Gerda Resch, re: Request for removal of PCIP from proposed sterilization changes submitted June 3, 1997
06/20/97 MIP		From: FDA, CDRH, Van Nakayarra. To: Gerda Reach, MiniMed. re: Informal telephone communication regarding issues of recent IDE revision submission. Action to be taken by Gerda Resch for clarification from Susan McConnell
06/20/97		Explant
06/30/97 MIP		To: FDA, CDRH. Van Nakayama. From: Gerda Resch, MiniMed. re: Additional information regarding submission dated 6/3197, change to current sterilization process (MMT-2001)
07/01/97 MIP	S165	From: FDA, CDRH-, Tim Ulatowski.. To: Gerda Reach, MiniMed. re: Approval of IDE supplement, proposing changes to sterilization process.
07/17/97 MIP		To: FDA, CDRH. From: Jean Charlson, MiniMed. re: IND information provided to CDRH for incorporation into IND31,981 Drug Master File concerning proposed changes
07/22/97		Explant
08/08/97 MIP		To: FDA, CDRH, IDE Mail Center From: Gerda Resch, MiniMed. re: submission of alternate sterilization process with regard to MiniMed Implantable Pump (PCIP).
08/15/97 MIP	S170	From: FDA, CDRH, Tom Ulatowski. To: Jean Charlson, MiniMed. re: notification of receipt of IDE supplement concerning purification process for HOE 21 PH U400 insulin.
08/22/97 MIP		To: FDA, CDRH, IDE Mail Center. From: Jean Charlson, MiniMed. re submission of follow-up to Adverse Event report dated 2/20/97, patient 1909JRR
09/04/97 MIP		To: FDA CDRH, IDE Mail Center. From: Gerda Resch, MiniMed. re: request for change to the sterilization process in the MiniMed Implantable Pump Side Port Catheter (MMT-4021-4028)

09/05/97 MIP		To: FDA, CDRH, IDE Mail Center. From: Gerda Resch, MiniMed. re: request for consideration to change manufacturing material for the MMT-4021-4028 Side Port Catheter
09/09/97 MIP		To: FDA, CDRH, IDE Mail Center. From: Gerda Resch, MiniMed. re: request for change in expiration dating of the MiniMed Implantable Pump (MMT-4105 Refill Kit)
09/11/97 MIP	S172	From: FDA Questions on PCIP sterilization
09/16/97 MIP	S173	From: FDA, CDRH, Timothy Ulatowski. To: Jean Charlson, MiniMed, re: approval of IDE supplement regarding a change in Catheter Flush Procedure. (use of 10cc or 20cc syringe)
09/24/97 MIP	S174	To: IDE Mail Center, FDA, CDRH-. From: Gerda Resch, MiniMed. re: request via fax for the withdrawal of supplement dated Sept 4, 1997 (alternate sterilization method Acrylic Side Port Catheter)
09/24/97 MIP	S175	To: IDE Mail Center, FDA, CDRH-. From: Gerda Resch, MiniMed. re: request via fax for the withdrawal of supplement dated Sept. 5, 1997 (Change in materials of the catheter connector)
09/29/97 MIP	S176	From: FDA, CDRH Mr. Tim Ulatowski. To: Gerda Resch, MiniMed. re: approval of request for change in expiration date of Pump Refill Kit, Model MMT-4105 from six months to two years.
10/01/97 MIP	S174	From: FDA, CDRH Mr. Tim Ulatowski. To: Gerda Resch, MiniMed. re: acceptance of request for withdrawal of supplement 174 dated Sept. 4, 1997
10/01/97 MIP	S175	From: FDA, CDRH Mr. Tim Ulatowski. To: Gerda Resch, MiniMed. re: acceptance of request for withdrawal of supplement 175 dated Sept. 5, 1997
10/24/97		Implant
10/24/97		Explant
10/24/97		Explant
10/24/97		Implant
10/27/97		Explant
11/07/97		Explant
11/07/97		Explant
11/25/97 MIP	S172	To: IDE Mail Center, CDRH, FDA. From: MiniMed. Gerda Resch. re: IDE supplement submission regarding MiniMed Implantable Pump - MMT-2001 - PCIP (sterilization process)
12/05/97		Implant
12/05/97		Explant
12/11/97 MIP	S178	From: FDA, CDRH Mr. Tim Ulatowski. Approval of proposed changes to the connector material, redesign of the catheter connector and change in sterilization gases with regard to the Side Port Catheter MMT-4021 – 4028
12/22/97 MIP	S179	From: FDA. CDRH, Mr. Tim Ulatowski. Approval of proposed changes to the sterilization technique for the MiniMed MMT-2001 PCIP
01/05/98		Explant
02/20/98		Explant
02/23/98 MIP		To: FDA, CDRH, Document Mail Center. re: Treatment IDE Submission for the MiniMed Implantable Pump System and Treatment IND Submission for HMR HOE 21 PH U-400 Insulin
03/03/98 MIP	S180	To: Mr. Von Nakayama, CDRH. re: Request to withdraw Treatment IDE application for the MiniMed Implantable Pump System submitted February 23, 1998
03/18/98		Explant

03/24/98 MIP		From: FDA, CDRH, IDE Progress Report Coordinator. re: Reminder of necessity to submit annual progress report due January 27, 1998
04/06/98 MIP		To: FDA, CDRH. Mr. Von Nakayama. From: Mr. Mark Faillace, Dir. Reg. Affairs. re: fax communication of a Draft letter to be sent to FDA, CDRH, regarding a request for closure of the supplement to IDE G860065.
04/14/98 MIP		To: IDE Mail Center, CDRH, FDA. re: Annual Progress Report to MiniMed Protocol 302
10/21/98 MIP	S181	To: FDA, CDER/CDRH, Ms. Julie Rhee/Mr. Von Nakayama. re: IDE 860065/IND 31,198; Supplement 181
01/19/99		Explant
01/19/99		Implant
01/19/99		Explant
01/19/99		Implant
01/29/99		Implant
01/29/99		Implant
01/29/99		Implant
01/29/99		Explant
01/29/99		Explant
02/03/99		Explant
02/16/99		Implant
02/16/99		Implant
03/03/99		Explant
03/03/99		Explant
03/16/99		Implant
03/16/99		Implant
04/13/99		Implant
04/13/99		Explant
04/13/99		Implant
04/21/99		Implant
04/21/99		Explant
04/21/99		Implant
04/22/99		Implant
04/22/99		Implant
04/22/99		Implant
04/30/99		Explant
05/11/99		Explant
05/11/99		Implant
05/11/99		Implant
06/01/99		Explant
06/01/99		Implant
06/01/99		Implant
06/01/99		Explant
06/03/99 MIP		From: FDA, CDRH. IDE, Mr. Peter Zaudtke. re: Reminder regarding Annual Progress Report for the Model MIP Programmable Implantable Insulin Pump
06/16/99		Implant
06/16/99		Explant
07/01/99 MIP		To: FDA. CDRH, IDE Document Mail Center. re: Supplement to IDE G860065, plan to utilize alternate configuration of MiniMed Implantable Pump

07/06/99		Explant
07/06/99		Explant
07/06/99		Implant
07/06/99		Implant
07/07/99		Implant
07/07/99		Explant
07/13/99 MIP		To: FDA, CDRH, Document Mail Center. re: MiniMed Implantable Pump (MIP), Model Series MIP Annual Progress Report
07/22/99		Implant
07/22/99		Explant
07/26/99 MIP	S184	From FDA. CDRH, ODE. Mr. Tim Ulatowski. re: Approval of manufacturing change to the MIP System; removal of Genapol PF10 coating
07/29/99		Implant
07/29/99		Explant
07/29/99		Explant
07/29/99		Implant
10/26/99		fax to Patent Cricenti of FDA regarding MiniMed's intention to submit PMA application for the MIP system
11/19/99		fax to Mary Joe Robinson of FDA with proposed agenda for meeting to discuss MIP systems PMA application
12/7/99		meeting between MiniMed representatives and FDA regarding MIP system PMA application
12/23/99		letter to Pat Cricenti of FDA regarding results of 12/7/99 meeting to discuss MIP system